FEB 2 1 2014 K132402

2. "510(k) Summary" as required by section 807.92(c)

Submitter:	Nonin Medical, Inc.
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Contact Person:	Brodie Pedersen Senior Regulatory Engineer
Date Prepared:	September 13, 2013
Trade Name:	Model X-100
Common Name/ Classification Name and Number:	Oximeter Class II, 21 CFR 870.2700
Product Code:	MUD, DQA
Predicate Device(s):	Nonin's SenSmart™ Model X-100 Universal Oximetry System is equivalent to the predicate Model 7600 system cleared by the FDA under K113215 on 5/18/2012 including the 8004CB and 8004CB-NA sensors, the Model 7600 cleared by the FDA under K102715 on 12/17/2010 including the 8004CA and 8000CA sensors, and Model 7500 Digital Pulse Oximeter and cleared by the FDA under K080255 on 5/23/2008. Nonin's Model 8100S(x) reusable soft sensor is equivalent to Nonin's predicate Model 8000S(x) reusable soft sensor cleared by the FDA with Model 7500 Digital Pulse Oximeter under K080255 on 5/23/2008 and in K092101 on 10/21/2009. Nonin's SenSmart Download Software is equivalent to Nonin's predicate eVISION Data Management Software cleared by the FDA in K092678. This software like eVISION is an optional accessory to the SenSmart Model X-100 Universal Oximeter system. As shown in Table 1 below, these devices represent the same technical characteristics as the subject device utilizing the same materials, power source and communication technology.

Device Description:

The SenSmart X-100 Oximetry System performs both pulse oximetry and regional oximetry measurements. The SenSmart X-100 Oximetry System works with all Nonin Equanox regional oximetry sensors (Model 8004CA, Model 8003CA, Model 8004CB and Model 8004CB-NA). The SenSmart compatible pulse oximetry Soft Sensor Model 8100S(x) is used with the Model X-100 System. The system consists of the sensor, the X-100SP signal processor (up to 6), extensions cables, the X-100H hub for multiple channels, the X-100M SenSmart Monitor which includes display, alarms, and memory. The SenSmart Download software is included for data storage review and reporting on a Windows PC.

Indications for Use:

Model X-100

Nonin's SenSmart™ Model X-100 Universal Oximetry System is a modular system and is indicated for use in simultaneously measuring, displaying, monitoring, and recording up to six (6) channels of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate or cerebral or somatic hemoglobin oxygen saturation (rSO2) of blood underneath the sensor. Patient populations include adult, pediatric, infant, and neonate through the use of SenSmart compatible sensors. The SenSmart system is intended for use in hospitals, long-term care, medical facilities, sleep laboratories, sub-acute environments, and Emergency Medical Services (EMS), including patient transport. The X-100 SenSmart system may be used for spot-checking and continuous monitoring with patient alarms. The SenSmart pulse oximetry (SpO2) functionality is suitable for use in both motion and non-motion conditions, including patients who are well or poorly perfused.

Model 8100S(x)

Nonin's Model 8100S(X) reusable soft sensor is indicated for non-invasive spot checking and/or continuous monitoring of adult and pediatric patients who are well or poorly perfused, during both motion and non-motion conditions. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care, and mobile environments.

SenSmart Download Software

The SenSmart Download Software is an optional accessory for use with Nonin's X-100M SenSmart Monitor only. It is intended for use by healthcare professionals when 1) transferring data from the X-100M to a computer in order to maintain individual records of oximetry data, 2) reviewing data according to user-selected parameters, and 3) generating reports.

Technological Characteristics:

The Model X-100 system is the Model 7600 platform with the addition of the SpO2 module and sensor from the Model 7500. The Model X-100 provides both modalities of oximetry monitoring in one monitor. The indications for use are combined from the predicate monitors with no changes from the predicates.

The Model X-100 system connectors are modified to prevent misconnection with incompatible components. The Model 8000S(x) connector was modified to create the Model 8100S(x) sensor, consistent with the Model 8004CX regional sensor connector. The Model X-100 system has undergone significant testing and evaluation as described below to assure there is no effect on safety or effectiveness. As shown in Table 1 below, these predicate devices represent the same technical characteristics as the subject device utilizing the same materials, power source and communication technology to provide regional oximetry and pulse oximetry in one device.

Table 1: Technological Characteristics

CATEGORY	Identical/ Different	Model X-100	Model 7600	Model 7500
INDICATIONS FOR USE	Similar	Nonin's SenSmart™ Model X-100 Universal Oximetry System is a modular system and is indicated for use in simultaneously measuring, displaying, monitoring, and recording up to six (6) channels of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate or cerebral or somatic hemoglobin oxygen saturation (rSO2) of blood underneath the sensor. Patient populations include adult, pediatric, infant, and neonate through the use of SenSmart compatible sensors. The SenSmart system is intended for use in hospitals, long-term care, medical facilities, sleep laboratories, sub-acute environments, and Emergency Medical Services (EMS), including patient transport. The X-100 SenSmart system may be used for spot-checking and continuous monitoring with patient alarms. The SenSmart pulse oximetry	Nonin's non-invasive Model 7600 4- Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor. It is intended for spot-checking or continuous monitoring of adult, or neonate, infant and pediatric patients. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.	The Nonin Model 7500 Digital Pulse Oximeter is a portable tabletop device indicated for use in measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, pediatric, infant and neonatal patients. It is indicated for spot checking and or continuous monitoring of patients during both motion and non-motion conditions, and for patients who are well or poorly perfused.

CATEGORY	Identical/ Different	Model X-100	Model 7600	Model 7500
		(SpO2) functionality is suitable for use in both motion and non-motion conditions, including patients who are well or poorly perfused.		
Indications for use	Similar	Nonin's Model 8100S(X) reusable soft sensor is indicated for non-invasive spot checking and/or continuous monitoring of adult and pediatric patients who are well or poorly perfused, during both motion and non-motion conditions. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care, and mobile environments.	NA	Nonin's Model 8000SX-Series Reusable Soft Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients who are well or poorly perfused. It is intended for use in environments including operating room, surgical recovery, critical care, emergency room, long-term care, home use, and mobile environments.
Indications for use	Similar	The SenSmart Download Software is an optional accessory for use with Nonin's X-100M SenSmart Monitor only. It is intended for use by healthcare professionals when 1) transferring data from the X-100M to a computer in order to maintain individual records of oximetry data, 2) reviewing data according to user-selected parameters, and 3) generating reports.	eVISION Data Management Software (eVISION) is an optional accessory for use with Nonin's Model 7600 Regional Oximeter System. It is intended for use by healthcare professionals when 1) transferring data from the X-100M to a computer in order to maintain individual records of oximetry data, 2) reviewing data according to user-selected parameters, and 3) generating reports.	The nVISION Data Management Software is an optional accessory for compatible Nonin oximeters: 2120, 2500, 3100, 3150, 4000 7500, 7800, 8500, 8800, 9600, 9700, and 9847. It is intended for use by healthcare professionals when (1) transferring data from pulse oximeters to computers in order to maintain individual records of pulse oximetry data, (2) reviewing data according to user-selected parameters, and (3) generating reports.
SYSTEM CONFIGURATIONS				
Parts and Accessories				

CATEGORY	Identical/ Different	Model X-100	Model 7600	Model 7500
Sensor Models	Similar	All Nonin smart sensors, 8004CA, 8003CA, 8004CB, 8004CB-NA, 8100S(x)	All Nonin Regional smart sensors, 8004CA, 8003CA, 8004CB, 8004CB-NA	All Nonin DE9 connector pulse oximeter sensors including Model 8000S(x)
Download software	Similar	SenSmart Download	eVISION	nVISION
Batteries	Similar	Li ION	Li ION	NiMH
Operator's instructions	Similar	CD	CD	CD
OVERALL SPECIFICATIONS				
SpO_2 Range	Similar	0% to 100% SpO2	NA	0% to 100% SpO2
rSO_2 Range	Similar	0% to 100% rSO2	0% to 100% rSO2	NA
Pulse Rate Range	Similar	18-321 BPM	NA	18-321 BPM
Accuracy				
rSO_2	Similar	8004CA 3.9 +/-A_{rms} absolute 8004CB 5.9 +/-A_{rms} absolute 8003CA 3.6 A_{rms} Trending	8004CA 3.9 +/-A_{rms} absolute 8004CB 5.9 +/-A_{rms} absolute 8003CA 3.6 A_{rms} Trending	NA
SpO_2	Similar	±2 digits (± 1 Arms)	NA	±2 digits (± 1 Arms)
Low Perfusion SpO_2	Similar	±2 digits (± 1 Arms)	NA	±2 digits (± 1 Arms)
Pulse Rate	Similar	20 to 250 BPM ±3 digits	NA	20 to 250 BPM ±3 digits
Low Perfusion Pulse Rate	Similar	40 to 240 BPM ±3 digits	NA	40 to 240 BPM ±3 digits
Displays				
	Similar	LCD Panel 6 Channels	LCD Panel 4 Channels	7-Segment 3-Digit LED 1 Channel
Connectivity				
	Identical	Saber Bluetooth Module	Saber Bluetooth Module	N/A
Package	Similar	Box	Box	Box

Testing:

Nonin's Model X-100 Oximeter system is supported by both laboratory and clinical hypoxia accuracy testing in order to ensure that it has appropriate performance and functional features to fully comply with recognized standards and is substantially equivalent to the predicate device.

Functional and Safety Testing:

Laboratory testing included: software verification, safety testing for electrical, mechanical, biocompatibility analysis, ingress protection, electromagnetic compatibility, device performance, usability evaluation, wireless Bluetooth certification and mechanical durability. These tests have been performed to demonstrate equivalency with the predicate devices and compliance with recognized standards. As shown in the table below the device met the relevant requirements of the applicable recognized standards.

rSO_2 Accuracy Testing

The rSO_2 accuracy was demonstrated through detailed device comparison and testing showing how the X-100SP is equivalent to the Model 7600PA pod used with the Model 7600 system regarding rSO2 measurements. The regional sensors are identical to those used with the 7600PA. The testing shows via the clinical data how the output from each system is the same when the input signals of the same magnitude as encountered during the clinical testing are utilized.

Test	Reference	Result
Electrical Safety	IEC 60601-1	Pass
Temperature and Humidity	IEC 60601-1	Pass
Cleaning	IEC 60601-1	Pass
Electromagnetic Immunity and Emissions	IEC 60601-1-2	Pass
Bluetooth Wireless certification	FCC wireless certification Grant	Pass
Performance	ISO 80601-2-61 IEC 60601-1 IEC 60601-1-6	Pass
Ingress Protection	ISO 80601-2-61	Pass
Mechanical Durability	ISO 80601-2-61	Pass
Atmospheric Pressure	IEC 60601-1	Pass
Usability	IEC 60601-1-6	Pass

Clinical Testing:

Clinical testing for SpO2 included induced laboratory hypoxia testing on healthy volunteers. A Usability / Human Factors Study was performed to get real user feedback from clinical oximeter users.

SpO2 Accuracy Testing

Clinical hypoxia accuracy testing conducted during induced hypoxia studies on 13 healthy, nonsmoking, light-to-dark-skinned subjects in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO2) of the device was compared to arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the device is in comparison to the co-oximeter samples measured over the SpO2 range of 70-100%. Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, Standard Specification for Pulse Oximeters for Accuracy in a non-motion environment demonstrated a specified accuracy of ±2% in non-motion conditions and ±3 in motion conditions on the index finger, middle finger, or ring finger for all data points with an arterial oxygen saturation (SaO2) of greater than or equal to 70%. There were no reported adverse effects during these investigations.

Objectives: The purpose of this study was to verify SpO2 performance accuracy of the Nonin Medical Model X-100SP oximeter with the 8100S(X), pulse oximetry sensors on the finger in stationary (non-motion) and motion conditions. These aims were achieved by comparing SpO2 measurements with those of arterial blood samples assessed by CO-oximetry. The study was designed in accordance with ISO 80601-2-61. The goal, in its entirety, was to show the SpO2 accuracy performance for the devices. It was expected that the Accuracy Root Mean Square (Arms) performance of the above pulse oximetry systems will meet a specification of ±3% for the range of 70 – 100% SaO2.

Methods: Subjects were connected to a breathing circuit, in which the gas flow delivery was adjusted for subject comfort. This gas circuit provided a gas mixture of medical grade oxygen and nitrogen. The program was run in manual mode, in which the gas mixture was changed by the controller. The program was used to induce hypoxia in a stair-stepped manner which allowed each subject to settle at his or her SpO2 level (e.g. plateau). At each plateau, arterial blood sampling was performed. After drawing a waste sample to clear the arterial line, an arterial sample was drawn. The beginning and end of each draw was noted on the data collection system. This series of waste draw, and arterial draws was repeated multiple times for each plateau. At the end of each plateau, the arterial line was flushed with sterile saline. Subsequently, the program was adjusted to allow the subject to reach a new level of SpO2 and the process was repeated. Samples were run on four (4) CO-oximeters. The SpO2 values at each draw were paired with the average of the three Radiometer CO-oximeters (ALB80Flex OSM).

On one hand (the hand without the arterial line), two types of motion were evaluated. These included tapping and rubbing. Both were induced using a motion simulator, occurring at a frequency of 1 Hz, and moving the fingers approximately 1-2 inches. Subjects alternated between starting with rubbing or tapping. Subsequently, the motion type alternated for each stable plateau.

Conclusions: The X-100SP (software rev. 12085) with 8100S(X) sensors demonstrated a specified accuracy of ±2% in non-motion conditions and ±3 in motion conditions on the index finger, middle finger, or ring finger for all data points with an arterial oxygen saturation (SaO2) of greater than or equal to 70%.

USABILITY: The testing performed for this Usability / Human Factors Study was to acquire user feedback from clinical oximeter users.

The primary objective of this study was to collect data which demonstrates the usability of the Nonin Model X-100 SenSmart™ system user interface. The usability components to be tested in this study included operator effectiveness, efficiency, and operator satisfaction. These were assessed by recording the proportion of users who properly performed each task, the time it took to perform each step, and the operator's perception of the system, respectively. Operator effectiveness was the primary objective. Efficiency and operator satisfaction were secondary objectives. Secondary endpoints are descriptive in nature.

Methods: Each user was asked about their knowledge of regional and pulse oximetry. They were trained on system use through an in-service conducted by Nonin personnel. The training included a demonstration of the functions of the system. A minimum of two days after training, each user returned to demonstrate system use. The users were presented with two case scenarios that used specific functions of the system. Users had the benefit of Instructions for Use and In-Service materials as well as the opportunity to contact their clinical education specialist as would be the case with normal clinical use. An observer was present to watch the user perform each task and document whether the tasks were performed appropriately, and whether the user had difficulty using the system. User responses and body language were also documented. The users then completed a questionnaire regarding the various aspects of using the Model X-100 system.

Usability validation was conducted with 20 health care professionals who performed the use case scenarios. A list of effectiveness endpoints which were met and unmet was provided. Lists of modifications to the device, in-service and accompanying documentation were provided. On average, users agreed or strongly agreed with all statements about system set-up except the ease of changing from %baseline to absolute

alarm limits. On average users also agreed or strongly agreed with all statements about system use.

Conclusion: The Model X-100 has been found to be suitable to provide operator effectiveness, efficiency, and operator satisfaction for the intended users, uses and environments.

Conclusion:

Nonin's SenSmart™ Model X-100 Universal Oximetry System is substantially equivalent to the Model 7600 cleared by the FDA under K113215 on 5/18/2012 including the 8004CB and 8004CB-NA sensors, the Model 7600 cleared by the FDA under K102715 on 12/17/2010 including the 8004CA and 8000CA sensors and Model 7500 Digital Pulse Oximeter and cleared by the FDA under K080255 on 5/23/2008.

Nonin's Model 8100S(x) reusable soft sensor is substantially equivalent to Nonin's Model 8000S(x) reusable soft sensor cleared by the FDA with Model 7500 Digital Pulse Oximeter under K080255 on 5/23/2008 and in K092101 on 10/21/2009.

Nonin's SenSmart Download Software is substantially equivalent to Nonin's eVISION Data Management Software cleared by the FDA in K092678. This software like eVISION is an optional accessory to the SenSmart Model X-100 Universal Oximeter system.

The positive results of testing, lead to the conclusion that the revised indications for use and labeling are substantially equivalent to the predicate device and do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Nonin Medical, Inc.
Mr. Brodie Pedersen
Senior Regulatory Engineer
13700 1st Avenue North
Plymouth, MN 55441-5443

Re: K132402
Trade/Device Name: SenSmart™ Model X-100 Universal Oximetry System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, MUD
Dated: January 17, 2014
Received: January 22, 2014

Dear Mr. Pedersen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

510(K) Number: K132402

Device Name:

Nonin Medical, Inc. Model X-100

Indications for Use:
Model X-100

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Todd D. Courtney -S
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